COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 50 | 8 June 2021

This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

LATEST KEY DEVELOPMENTS

Competition & State Aid

- European Commission President von der Leyen speaks before European Parliament on Recovery and Resilience plans
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- EU submits proposal to WTO on global trade approach to vaccine access

Medicines and Medical Devices

- BioNTech/Pfizer: First COVID-19 vaccine in EU approved for children aged 12 to 15
- EMA commences evaluation of use of Moderna COVID-19 vaccine Moderna in youth aged 12 to 17

Cybersecurity, Privacy & Data Protection

- European Commission proposes framework for a European Digital Identity

COMPETITION & STATE AID	
State Aid	
European Commission President von der Leyen speaks before European Parliament on Recovery and Resilience plans (see here)	On 8 June 2021, Commission President Ursula von der Leyen spoke at the European Parliament ("EP") Plenary regarding the EP's scrutiny of the ongoing assessment by the Commission and the Council of national Recovery and Resilience Plans. As of 8 June 2021, the Commission had received plans from 23 Member States (*see also Jones Day COVID-19 Update No. 49 of 2 June 2021).* These Member State plans set out the reforms and public investment projects foreseen for implementation with the support of the Recovery and Resilience Facility (RRF), the key component of NextGenerationEU, the EU's plan for rebounding from the COVID-19 crisis. The RRF will provide up to €672.5 billion to finance reforms and investments (i.e., grants totaling €312.5 billion and €360 billion in loans). The RRF guidelines, notably, make clear that the investment projects included in Member State recovery plans must comply with State aid rules. (*Jones Day Commentary, "EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, see here*). President von der Leyen emphasized that the 27 Member States have devoted significant effort to developing these plans, along with some 300 European Commission colleagues who have been working on these plans virtually "*around the clock*," together with their national counterparts. Regarding the EP's role, President von der Leyen referred to its valuable review and feedback on Member State plans. She indicated that the Commission would continue to meet regularly with the EP for structured dialogue on the plans. President von der Leyen stated that as of the week of 14 June 2021, the Commission would commence approving the first Member State plans for Council adoption.
European Commission approves new and amended Member State measures to support the economy (see here and here)	Since the onset of the coronavirus outbreak, the Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the Temporary Framework. The most recent measures adopted to support the economy and companies affected by coronavirus outbreak include: • €58.8 million Belgian wage subsidy schemes to support employers in travel, hotel and events sectors affected by the coronavirus outbreak. • €4 million Estonian scheme to support commercial regular bus services companies affected by the coronavirus outbreak. • €500,000 Portuguese scheme to support passenger transport sector in the Azores in the context of the coronavirus outbreak. • €95 million Austrian wage subsidy scheme to support companies in the context of the coronavirus outbreak. • €800 million Polish receivable insurance scheme to support domestic

trade credit in the context of the coronavirus outbreak.

- Commission approves modifications of Polish scheme to support companies in the tourism and cultural sectors affected by the coronavirus outbreak, resulting in €593 million budget increase.

TRADE / EXPORT CONTROLS

EU submits proposal to WTO on global trade approach to vaccine access (see here)

On 4 June 2021, the EU submitted a proposal to the World Trade Organization (WTO), composed of two Communications, aimed at a holistic global trade approach to universal vaccination in combating the pandemic.

The first Communication, "Urgent Trade Policy Responses to the COVID-19 Crisis," (see here) primarily aims at ensuring equitable access to vaccines worldwide and raises the following key elements:

1. Ensuring that COVID-19 vaccines can cross borders freely by limiting current export restrictions and facilitating trade;
2. Encouraging producers to expand their vaccine production, while ensuring that low-income countries can receive them at an affordable price;
3. Addressing intellectual property rights ("IPR") issues, in particular towards facilitating the use of compulsory licensing by governments, as envisaged by the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").

The second Communication, "Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property" (see here) further details the above-mentioned IPR issues.

The Communication takes a targeted approach, unlike the broad waiver on IPR for COVID-10 vaccines advocated by several countries (most notably India and South Africa, which proposed such waiver in Oct. 2020), and for which the US also recently expressed support (*see also Jones Day COVID-19 Update No. 48 of 26 May 2021*).

The EU indicates its view that voluntary licenses are the most effective instrument to expand production and share necessary know-how. However, in the absence of voluntary licenses, the EU also advocates that compulsory licenses are an appropriate means to prevent IPR from ramping up production during the pandemic, given the following:

1. the circumstance of national emergency and therefore the ability to renounce the requirement to negotiate with IPR holder;
2. the need to support manufacturers ready to produce vaccines or treatments at affordable prices under a compulsory license; and
3. a compulsory license could cover any exports to countries that lack manufacturing capacity, including via COVAX.

In July 2021, the WTO General Council is expected to open discussions on a process focused on trade and health-related issues. This discussion should conclude in November 2021 at the latest, during the next WTO Ministerial Conference.

MEDICINES AND MEDICAL DEVICES

BioNTech/Pfizer: First COVID-19 vaccine in EU approved for children aged 12 to 15 (see here)	On 28 May 2021, the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") issued a positive opinion on the application to extend the marketing authorization of the BioNTech/Pfizer COVID-19 vaccine (Comirnaty) to include use in children aged 12 to 15. The vaccine was approved on 21 December 2020 for use in adults and adolescents aged 16 and above. The extended use of the Comirnaty vaccine was granted through an accelerated assessment, given the major public health interest of the product. Comirnaty's efficacy was assessed in some 2,000 children from 12 to 15 years of age who had no sign of previous infection. In this study, the vaccine was 100% effective at preventing COVID-19. However, the EMA noted that the true rate could be between 75% and 100%. The EMA will publish an assessment report, with details of its evaluation of use of Comirnaty in children. Clinical trial data submitted by the company in the application for the pediatric extension of indication will be published in due course on the EMA's Clinical Data website.
EMA commences evaluation of use of Moderna COVID-19 vaccine Moderna in youth aged 12 to 17 (see here)	On 8 June 2021, the EMA commenced the evaluation of extending use of the Moderna COVID-19 vaccine to include youth aged 12 to 17. The vaccine was approved on 6 January 2021 for use in adults aged 18 years and older. EMA's human medicines committee, CHMP, will undertake an accelerated assessment of data submitted in the application, including results from a large ongoing clinical study involving adolescents from 12 to 17 years of age. The CHMP's recommendation on extending use of the vaccine, together with any requirements for further studies and additional safety monitoring, will be provided to the European Commission, which will issue a final legally binding decision applicable across the EU. EMA expects to communicate the outcome of its evaluation in July 2021, unless supplementary information is required.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission proposes framework for a European Digital Identity (see here)	On 3 June 2021, the Commission released its proposed framework for a European Digital Identity. This includes a Proposal for a Regulation establishing a framework for a European Digital Identity (see here), as well as a Recommendation on a common Union Toolbox for a coordinated approach towards a European Digital Identity Framework (see here). The Commission also issued questions and answers ("Q&A") on the proposed framework (see here). Under the proposed Regulation, all EU citizens, residents, and businesses would benefit from European Digital Identity Wallets, which will help to prove their identity and share electronic documents (e.g., for online banking or other online services). The Commission noted the urgency of this proposal in the context of the pandemic, which has accelerated the need for effective and user-friendly digital services across the EU.

Users of European Digital Identity Wallets would have control over what personal data they choose to share with online services. For instance, users could download, store and use their basic personal data, a driving license, a diploma, or a bank card that they presently carry as physical cards in their physical wallets.

According to the proposed Regulation, a high level of security would be ensured. In particular, the Commission will propose and agree with Member States on standards, technical specifications and operational aspects. Wallets would be certified by Member States to comply with these security requirements, and personal data would be shared online only if the user chose to share that information.

Additionally, the Recommendation urges Member States to immediately commence preparations to establish a common "Toolbox", which should include the technical architecture, standards and guidelines for best practices to support implementation of the European Digital Identity framework.

For example, Member States should identify common standards and technical references for European Digital Identity Wallets user functionalities, such as the use of qualified electronic signatures and communication of security breaches.

By October 2022, following close cooperation with Member States, the Commission aims at publishing the Toolbox to implement the European Digital Identity Framework. Following agreement on the technical framework, it can be tested in pilot projects.

LAWYER CONTACTS

Renato Antonini
Partner, Government Regulation; Antitrust & Competition Law
Brussels
rantonini@jonesday.com
+32.2.645.14.19

Dr. Jörg Hladjk
Partner, Cybersecurity, Privacy & Data Protection; Government Regulation; Technology
Brussels
jhladjk@jonesday.com
+32.2.645.15.30

Kaarli H. Eichhorn
Partner, Antitrust & Competition Law; Government Regulation; Technology
Brussels
keichhorn@jonesday.com
+32.2.645.14.41

Cristiana Spontoni
Partner, Health Care & Life Sciences; Government Regulation
Brussels
cspontoni@jonesday.com
+32.2.645.14.48